

Notice of Allowability

Application No.

10/727,155

Examiner

Zachary Skelding

Applicant(s)

BABCOOK ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 1, 2006, February 22, 2007 and March 5, 2007.
2. ☒ The allowed claim(s) is/are 58,61,63-66,69,73,76,78-80,83,86 and 107-127.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2-22-07, 3-5-07</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment to the claims filed December 1, 2006 has been entered.

EXAMINER'S AMENDMENT

2. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.
3. Authorization for this Examiner's Amendment was given in telephone interviews with Brent C. Moore on February 22, 2007 and March 5, 2007.
4. **Please replace the Sequence Listing filed December 2, 2003 in conjunction with the instant application with the Substitute Sequence Listing filed on December 1, 2006.**
5. **Cancel claims 88-90.**
6. **Please amend claims 58, 66, 73, 83 and 110-122 as follows:**

58. (Currently Amended) A fully human monoclonal antibody, or binding fragment thereof, comprising a light chain comprising the amino acid sequence of SEQ ID NO: 72 and a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 74 and wherein said antibody or said binding fragment thereof binds to human Tumor Necrosis Factor- α .

66. (Currently Amended) A fully human monoclonal antibody, or binding fragment thereof, comprising a light chain comprising the amino acid sequence of SEQ ID NO: 72 and a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 70 and wherein said antibody or said binding fragment thereof binds to human Tumor Necrosis Factor- α .

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73. (Currently Amended) A fully human monoclonal antibody, or binding fragment thereof, comprising a light chain comprising the amino acid sequence of SEQ ID NO: 50 and a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 52 and wherein said antibody or said binding fragment thereof binds to human Tumor Necrosis Factor- α .

83. (Currently Amended) A fully human monoclonal antibody, or binding fragment thereof, comprising a light chain comprising the amino acid sequence of SEQ ID NO: 54 and a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 56 and wherein said antibody or said binding fragment thereof binds to human Tumor Necrosis Factor- α .

110. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 66, wherein said binding fragment comprises a Fab, Fab', F(ab')₂, or Fv fragment.

111. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 66, wherein said antibody has an IgG2 isotype.

112. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 58, wherein said binding fragment comprises a Fab, Fab', F(ab')₂, or Fv fragment.

113. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 58, wherein said antibody has an IgG2 isotype.

114. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 73, wherein said binding fragment comprises a Fab, Fab', F(ab')₂, or Fv fragment.

115. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 73, wherein said antibody has an IgG2 isotype.

116. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 83, wherein said binding fragment comprises a Fab, Fab', F(ab')₂, or Fv fragment.

117. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 83, wherein said antibody has an IgG2 isotype.

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118. (Currently Amended) A fully human monoclonal antibody, or binding fragment thereof, that binds to Tumor Necrosis Factor- α , wherein the antibody, or binding fragment thereof, comprises:

a heavy chain complementarity determining region 1 (CDR1) ~~having~~ comprising the amino acid sequence of "Ser Tyr Asp Met His" (SEQ ID NO: 321);

a heavy chain complementarity determining region 2 (CDR2) ~~having~~ comprising the amino acid sequence of "Val Ile Trp Ser Asp Gly Ser Ile Lys Tyr Tyr Ala Asp Ser Val Lys Gly" (SEQ ID NO: 322);

a heavy chain complementarity determining region 3 (CDR3) ~~having~~ comprising the amino acid sequence of "Glu Val Glu Ser Ala Met Gly Gly Phe Tyr Tyr Asn Gly Met Asp Val" (SEQ ID NO: 323);

a light chain complementarity determining region 1 (CDR1) ~~having~~ comprising the amino acid sequence of "Arg Ala Ser Gln Gly Ile Arg Ile Asp Leu Gly" (SEQ ID NO: 324);

a light chain complementarity determining region 2 (CDR2) ~~having~~ comprising the amino acid sequence of "Ala Ala Ser Thr Leu Gln Ser" (SEQ ID NO: 325); and

a light chain complementarity determining region 3 (CDR3) ~~having~~ comprising the amino acid sequence of "Leu Gln His Lys Ser Tyr Pro Leu Thr" (SEQ ID NO: 326).

119. (Currently Amended) The antibody, or binding fragment thereof, of Claim 118, wherein the antibody, or binding fragment thereof, comprises a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 70 and a light chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 72.

120. (Currently Amended) The antibody, or binding fragment thereof, of Claim 118, wherein the antibody, or binding fragment thereof, comprises a heavy chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 74 and a light chain polypeptide ~~having~~ comprising the amino acid sequence of SEQ ID NO: 72.

121. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 118, wherein said binding fragment comprises a Fab, Fab', F(ab')₂, or Fv fragment.

122. (Currently Amended) The fully human monoclonal antibody or binding fragment of Claim 118, wherein said antibody has an IgG2 isotype.

REASONS FOR ALLOWANCE

7. The following is an Examiner's Statement of Reasons for Allowance:

Applicant's amendment to the claims and arguments of December 1, 2006 obviated the previous rejections of record.

Moreover, in a telephone interview with Brent C. Moore on February 22, 2006, Applicant agreed to amend the claims to clarify the transitional language and antecedent basis for some of the dependent claims.


Furthermore, during this telephone conversation applicant was informed that while the instant specification supports the use of the anti-TNF- α antibodies comprising SEQ ID NOs: 72 and 74 or SEQ ID NOs: 72 and 70 or SEQ ID NOs: 50 and 52 to deliver a therapeutic agent to a cell and thereby treat, for example rheumatoid arthritis (see instant specification, pages 72-73 and 109), *the instant specification does not provide sufficient support for the use of the anti-TNF- α antibody comprising amino acid SEQ ID NOs: 54 and 56 to deliver a therapeutic agent to a cell.* Applicant indicated that, solely in the interest of facilitating further prosecution, they would agree to cancellation of claims 88-90 by Examiner's Amendment.

8. **Claims 58, 61, 63-66, 69, 73, 76, 78-80, 83, 86 and 107-127 are allowed.**
9. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
March 5, 2007


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